



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove a warning for growing cattle on pasture or in dry lot and to codify all monensin free-choice Type C medicated feeds in 21 CFR part 558. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA has noticed that the animal drug regulations for certain monensin free-choice Type C medicated feeds for growing cattle on pasture or in dry lot (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers) reflect a warning statement regarding the overdosing risk posed by uneaten free-choice feeds (refusals) that is unnecessary and not required on product labeling.

Refusals of free-choice cattle feeds, including compressed blocks, granules, and liquids, are unlikely in practice to be fed to another group of cattle. These products are used almost exclusively in pasture-based systems where the product is placed in the pasture with the animals and is left until consumed. In addition, it is extremely unlikely that these free-choice cattle feeds would be fed to another production class because these products generally are not appropriate for the nutritional needs of another production class.

For these reasons, FDA is revising the regulations to exclude monensin free-choice Type C medicated feeds for growing cattle on pasture or in dry lot from the requirement to include a warning statement. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects

##### 21 CFR Part 520

Animal drugs.

##### 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

#### PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§§ 520.1448 and 520.1448a [Removed]

2. Remove §§ 520.1448 and 520.1448a.

#### PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. In § 558.355, revise paragraphs (d)(7)(vii), (d)(10)(i), and (d)(10)(ii); remove and reserve paragraph (f)(3)(v); redesignate paragraph (f)(7) as paragraph (f)(8); and add new paragraph (f)(7) to read as follows:

§ 558.355 Monensin.

\* \* \* \* \*

(d) \* \* \*

(7) \* \* \*

(vii) If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing (see paragraphs (d)(10)(i) and (d)(10)(ii) of this section).

\* \* \* \* \*

(10) \* \* \*

(i) Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section): See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

(ii) Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section): See paragraphs (d)(6), (d)(7)(i), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

\* \* \* \* \*

(f) \* \* \*

(7) Free-choice feeds--(i) Amount. 150 milligrams per pound of protein-mineral block (0.033 percent).

(a) [Reserved]

(b) Conditions of use--(1) Indications for use. For increased rate of weight gain; and for prevention and control of coccidiosis caused by Eimeria bovis and E. zuernii in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) which may require supplemental feed.

(2) Limitations. Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds of block) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(ii) Amount. 400 milligrams per pound of protein-mineral block (0.088 percent).

(a) Sponsor. See No. 067949 in § 510.600(c) of this chapter.

(b) Conditions of use--(1) Indications for use. For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(2) Limitations. Provide 80 to 200 milligrams of monensin (0.2 to 0.5 pounds of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iii) Amount. 175 milligrams per pound of protein-mineral block (0.038 percent).

(a) Sponsor. See No. 066071 in § 510.600(c) of this chapter.

(b) Conditions of use--(1) Indications for use. For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder).

(2) Limitations. Provide 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day, at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iv) Amount. 400 milligrams per pound of block (0.088 percent).

(a) Sponsor. See No. 051267 in § 510.600(c) of this chapter.

(b) Conditions of use--(1) Indications for use. For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(2) Limitations. Provide 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or

mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

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Dated: September 13, 2012.

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